



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

(CD)

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/807,663 | 07/02/2001 | Antonio A. Garcia | A32011-A-PCT | 2220 |
| 21003 | 7590 | 05/06/2004 | EXAMINER | |
| BAKER & BOTTS 30 ROCKEFELLER PLAZA NEW YORK, NY 10112 | | | TRAN, MY CHAU T | |
| | | ART UNIT | PAPER NUMBER | 1639 |
| DATE MAILED: 05/06/2004 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/807,663 | GARCIA ET AL. |
| | Examiner | Art Unit |
| | MY-CHAU T TRAN | 1639 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 17 February 2004.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-9 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/17/04 has been entered.

Status of Claims

2. Applicant's amendment filed 12/16/03 is acknowledged and entered. Claims 10-23 have been canceled. Claims 1 and 5 have been amended.
3. Claims 1-9 are pending.
4. This application is a 371 of PCT/US99/23,902 filed 10/14/1999, which claims priority to two provisional applications. They are 60/104,263, filed 10/14/1998, and 60/145,786, filed 7/27/1999.

Withdrawn Objections and /or Rejections

5. In view of applicant's amendment of claim 1, the rejection of claim 1 under 35 USC 102(b) as anticipated by Kim et al. (*Biotechnol. Prog.*, 1995, 11(4):465-467) has been withdrawn.

6. In view of applicant's amendment of claim 5, the rejection of claims 5-9 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as being obvious over Kim et al. (*Biotechnol. Prog.*, 1995, 11(4):465-467) has been withdrawn.

7. In view of applicant's amendment of claim 5, the rejection of claims 5-9 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as being as obvious over Siiman et al. (US Patent 5,552,086) has been withdrawn.

8. In view of applicant's amendment of claim 1, the rejection of claims 1-4 under 35 USC 103(a) as being obvious over Kim et al. (*Biotechnol. Prog.*, 1995, 11(4):465-467) in view of Longiaru et al. (US Patent 5,232,829) has withdrawn.

Maintained Rejections

Claim Rejections - 35 USC § 102

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Siiman et al. (US Patent 5,552,086). (*Note: The rejection has been modified to address the new limitation of claim 1.*)

The instant claim 1 recites an apparatus (plate) comprise of silver ions immobilized on a support, wherein the plate is substantially transparent. The plate comprise of polystyrene plate (claim 2).

Siiman et al. disclose a device that comprises a metal coated polymer support that is in a bioassay (col. 1, lines 32-36; col. 2, lines 50-61). The polymer includes polystyrene (col. 7, lines 35-38). The metal includes silver salt (col. 7, lines 49-57). The surface of the substrate comprises metal oxide state (col. 5, lines 25-28 and lines 42-45; col. 7, lines 49-57). The metal coating on the support would provide an advantage of enhancing light scattering with excitation in the visible light region (col. 2, lines 58-60). Additionally, the silver coated polystyrene micropheres are coated onto the glass slide via a uniform coating (col. 13, lines 31-38). Therefore, the device of Siiman et al. anticipates the presently claimed invention.

Response to Arguments

11. Applicant's argument(s) directed to the above rejection under 35 USC 102(b) as being anticipated by Siiman et al. (US Patent 5,552,086) for claims 1-2 was considered but they are not persuasive for the following reasons.

Applicant contends that Siiman et al. does not anticipate the presently claimed invention because the surface of the Siiman et al. device comprise of “[a]minodextran, and not silver metal or silver oxide”.

Applicant's arguments are not convincing since the claimed apparatus of claim 1 comprises a support with silver ion immobilized thereon (i.e. the “top” layer of the support is silver ion). The surface of the Siiman et al. device is comprise of metal such as silver ions (col. 5, lines 25-28) (i.e. the “top” layer of the support is silver ion). Additionally, the comprising terminology of the claimed apparatus of claim 1 is open-ended and would not exclude “aminodextran” of the device of Siiman et al. Thus, the device of Siiman et al. anticipates the

presently claimed invention because it meets all the structural limitation of the claimed apparatus.

Claim Rejections - 35 USC § 103

12. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

13. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siiman et al. (US Patent 5,552,086) and Longiaru et al. (US Patent 5,232,829). (*Note: The rejection has been modified to address the new limitation of claim 1.*)

The instant claim 1 recites an apparatus (plate) comprise of silver ions immobilized on a support, wherein the plate is substantially transparent. The plate comprise of polystyrene plate (claim 2).

Siman et al. disclose a device that comprises a metal coated polymer support that is in a bioassay (col. 1, lines 32-36; col. 2, lines 50-61). The polymer includes polystyrene (col. 7, lines 35-38). The metal includes silver salt (col. 7, lines 49-57). The metal coating on the support would provide an advantage of enhancing light scattering with excitation in the visible light region (col. 2, lines 58-60).

The device of Siiman et al. does not expressly disclose that the support is in a plate format that is 96 wells.

Longiaru et al. disclose an immunoassay that comprise of a polystyrene solid support that has enhanced protein binding capacity (col. 3, lines 13-17; col. 6, lines 3-5). The polystyrene solid support is a microtitre plate with 96 wells (col. 7, lines 38-45). The plate capture format

would provide the advantages of a quicker assay time and a less labor intensive assay format (col. 3, lines 34-38).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a support in a plate format that is 96 wells as taught by Longiaru et al. in the device of Kim et al. One of ordinary skill in the art would have been motivated to include a support in a plate format in the device of Kim et al. for the advantage of a quicker assay time and a less labor intensive assay format (Longiaru: col. 3, lines 34-38) since both Kim et al. and Longiaru et al. disclose a polymer support is use in a bioassay (Siiman: col., lines 6-16; Longiaru: col. 6, lines 3-5). Furthermore, one of ordinary skill in the art would have reasonably expectation of success in the combination of Siiman et al. and Longiaru et al. because the support in a 96 wells plate format is well known (i.e. commercially available) and routinely use for bioassay (col. 7, lines 38-45).

Response to Arguments

14. Applicant's argument directed to the above rejection under 35 USC 103(a) as being unpatentable over Siiman et al. (US Patent 5,552,086) and Longiaru et al. (US Patent 5,232,829) for claims 1-4 was considered but they are not persuasive for the following reasons.

Applicant argues that neither Siiman et al. nor Longiaru et al. teaches the limitation of 'wherein the plate is substantially transparent' and there is no "[e]xpectation of success to make the asserted combinations". Therefore, the combination of Siiman et al. and Longiaru et al. is not obvious over the presently claimed apparatus.

Applicant's arguments are not convincing since the combination of Siiman et al. and Longiaru et al. is obvious over the presently claimed apparatus. The functionally limitation of the plate (i.e. the plate is substantially transparent) does not distinguish the presently claimed apparatus because Siiman et al. and Longiaru et al. meets all the structural limitation of the claimed apparatus (i.e. a 96-wells polystyrene plate with immobilized silver ion). Additionally, it has been held that 'While features of an apparatus may be recited either structurally or functionally, claims directed to >an< apparatus must be distinguished from the prior art in terms of structure rather than function. >*In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997) (The absence of a disclosure in a prior art reference relating to function did not defeat the Board's finding of anticipation of claimed apparatus because the limitations at issue were found to be inherent in the prior art reference); see also *In re Swinehart*, 439 F.2d 210, 212-13, 169 USPQ 226, 228-29 (CCPA 1971);< *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). "[A]pparatus claims cover what a device is, not what a device does."

Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (emphasis in original). (See MPEP 2114). Furthermore, there is reasonably expectation of success in the combination of Siiman et al. and Longiaru et al. because the support in a 96 wells plate format is well known (i.e. commercially available) and routinely use for bioassay (col. 7, lines 38-45). Thus, the combination of Siiman et al. and Longiaru et al. is obvious over the presently claimed apparatus.

New Rejections – Necessitated by Amendment

Claim Rejections - 35 USC § 112

15. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

16. Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase “substantially transparent” of claim 1 and 5 is considered indefinite because it is unclear as to the means of measuring the degree of “substantially transparent” (i.e. how does one measure “substantially transparent”). Note that if the scope of the invention sought to be patented cannot be determined from the language of the claims with a reasonable degree of certainty, a rejection of the claims under 35 U.S.C. 112, second paragraph is appropriate. In re Wiggins, 488 F.2d 538, 179 USPQ 421 (CCPA 1973).

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

19. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garcia et al. (*Reactive Polymers*, 1994, 23(2-3):249-259) and Temeyer et al. (US Patent 4,945,057).

Garcia et al. disclose an apparatus and the method of immobilizing silver ion on a polymer support for metal ion protein binding (Abstract; pg. 250, left col., lines 24-34, and right col., lines 17-43). The immobilization of the silver ion on the support comprises a two steps activation of the polymer support with glutaraldehyde and thiourea (pg. 250, right col., lines 22-43).

The apparatus of Garcia et al. does not expressly include a polymer support that is a polystyrene 96-wells plate.

Temeyer et al. disclose an immunoassay using a commercially available polystyrene plate (col. 7, lines 25-43). The polystyrene plate is activated using glutaraldehyde in order to attach the antigen (protein) onto the support.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a polymer support that is a polystyrene 96-wells plate as taught by Temeyer et al. in the apparatus of Garcia et al. One of ordinary skill in the art would have been motivated to include a polymer support that is a polystyrene 96-wells plate in the apparatus of Garcia et al. for the advantage of a support format that would provide a quicker assay time, and less labor intensive assay format since both Garcia et al. and Temeyer et al. disclose the method of attaching proteins to a polymer support (Garcia: pg. 250, left col., lines 24-34; Temeyer: col.

7, lines 25-29). Furthermore, one of ordinary skill in the art would have reasonably expectation of success in the combination of Garcia et al. and Temeyer et al. because the support in a 96 wells plate format is well known (i.e. commercially available) and routinely use for bioassay (col. 7, lines 38-45).

20. Claims 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garcia et al. (*Reactive Polymers*, 1994, 23(2-3):249-259) and Temeyer et al. (US Patent 4,945,057).

Garcia et al. disclose an apparatus and the method of immobilizing silver ion on a polymer support for metal ion protein binding (Abstract; pg. 250, left col., lines 24-34, and right col., lines 17-43). The immobilization of the silver ion on the support comprises a two steps activation of the polymer support with glutaraldehyde and thiourea (pg. 250, right col., lines 22-43).

It is noted that the instant claims (claims 5-9) are written as product-by-process claims. "Even though the product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claims is same or obvious from the product of the prior art, the claim is unpatentable even though the prior art product was made by a different process." In re Thorpe, 777F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). (see MPEP 2113).

The apparatus of Garcia et al. does not expressly include a polymer support that is a polystyrene 96-wells plate.

Temeyer et al. disclose an immunoassay using a commercially available polystyrene plate (col. 7, lines 25-43). The polystyrene plate is activated using glutaraldehyde in order to attach the antigen (protein) onto the support.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a polymer support that is a polystyrene 96-wells plate as taught by Temeyer et al. in the apparatus of Garcia et al. One of ordinary skill in the art would have been motivated to include a polymer support that is a polystyrene 96-wells plate in the apparatus of Garcia et al. for the advantage of a support format that would provide a quicker assay time, and less labor intensive assay format since both Garcia et al. and Temeyer et al. disclose the method of attaching proteins to a polymer support (Garcia: pg. 250, left col., lines 24-34; Temeyer: col. 7, lines 25-29). Furthermore, one of ordinary skill in the art would have reasonably expectation of success in the combination of Garcia et al. and Temeyer et al. because the support in a 96 wells plate format is well known (i.e. commercially available) and routinely use for bioassay (col. 7, lines 38-45).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MY-CHAU T TRAN whose telephone number is 571-272-0810. The examiner can normally be reached on Mon.: 8:00-2:30; Tues.-Thurs.: 7:30-5:00; Fri.: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANDREW WANG can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mct
May 3, 2004



PADMASHRI PONNALURI
PRIMARY EXAMINER